UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

29/OCT/2014

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for LIBERTY BIFEN FC

Subject:	Name of Pesticide Product:	LIBERTY BIFEN FC
	EPA File Symbol:	89168-GA
	DP Barcode:	D421653
	Decision No.:	491981
	Action Code:	R310
	PC Codes:	128825 Bifenthrin

From: Tracy Keigwin, Biologist
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

Mary Keegan

Hasbrouck
Team Leader - Tox

To: Kable Davis
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)

Applicant: Liberty Crop Protection, LLC
1966 W 15th Street, Suite 6
Loveland, CO 80538

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Bifenthrin	17.15
Other Ingredient(s):	82.85
Total:	100.00%

ACTION REQUESTED: The Risk Manager requests a review of data submitted in support of LIBERTY BIFEN FC, EPA File Symbol 89168-GA.

BACKGROUND: Liberty Crop Protection, LLC has submitted an application for the registration of EPA File Symbol 89168-GA, Liberty Bifen FC. In support of their application the registrant has submitted the following acute toxicity studies: MRID Nos. 49397904 (870.1100), 49397905 (870.1200), 49397906 (870.1300), 49397907 (870.2400), 49397908 (870.2500), and 49397909 (870.2600). The product label states that Liberty Bifen FC is "for mixing directly with liquid fertilizer to control listed soil insect pests". Note that this is a Restricted Use Pesticide due to toxicity to fish and aquatic organisms.

GLP: All studies were conducted in accordance with GLP.

DEVIATIONS: None

COMMENTS AND RECOMMENDATIONS:

1) The 6 submitted studies are acceptable. The acute toxicity profile of EPA File Symbol 89168-GA, Liberty Bifen FC is as follows:

acute oral toxicity	II	Acceptable	MRID 49397904
acute dermal toxicity	III	Acceptable	MRID 49397905
acute inhalation toxicity	IV	Acceptable	MRID 49397906
primary eye irritation	III	Acceptable	MRID 49397907
primary skin irritation	III	Acceptable	MRID 49397908
dermal sensitization	YES	Acceptable	MRID 49397909

2) We are requiring the use of protective eyewear based on the grade 3 redness and/or chemosis observed in the primary eye irritation study (MRID 49397907) from the one hour observation through the day 4 observation. This protective eyewear requirement should appear in both the precautionary statements and the Agricultural Use Requirements box.

3) The product chemistry team must approve the proposed Basic formulation (dated 5-27-2014) before this action can be finalized.

4) The following are the precautionary and first aid statements for this product, as obtained from the Label Review System:

PRODUCT ID #: **89168-GA (89168-36)**

PRODUCT NAME: **Liberty Bifen EC**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **WARNING**

SPANISH SIGNAL WORD: **AVISO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear: protective eyewear, long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Reviewer: Tracy Keigwin
Risk Manager (EPA): 10

Date: October 29, 2014

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted in support of EPA Reg. No. 89168-GA:

1. DP BARCODE: 421653				
2. PC CODES: 128825 Bifenthrin				
3. CURRENT DATE: October 29, 2014				
4. TEST MATERIAL: Liberty Bifen FC (Lot# SLH38-68-28; PSL Reference Number 140[illegible]28-7R; Purity: 17.44% Bifenthrin%; Light amber, slightly viscous liquid; pH 7.60 (as a 1% w/w[illegible] solution)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat PSL (Dayton, NJ) Study #38376/May 14, 2014 OCSPP 870.1100; OECD 425	49397904	LD_{50} Females=98.11 mg/kg bw. At 55 mg/kg (3 rats) all survived. Following dosing, reduced fecal volume (1/3) and nasal discharge (1/3) was observed. Affected animals recovered by study day 2. One female lost weight from day 7 to day 14. The remaining animals gained weight for the duration of the study. No gross abnormalities were observed at necropsy. At 175 mg/kg (3 rats) all animals died within one day of dosing. Test subjects exhibited irregular respiration, slight tremors and/or nasal discharge prior to death. At necropsy, decedents exhibited a distended stomach and/or intestines. A mottled, pale liver was additionally noted in one rat. At the 2000 mg/kg dose level the single animal tested died within 5 hours of dosing. Prior to death this animal exhibited irregular respiration and moderate tremors. At necropsy the decedent exhibited a slightly distended stomach.	II	A
Acute dermal toxicity / rat PSL (Dayton, NJ) Study #38377/May 14, 2014 OCSPP 870.1200; OECD 402	49397905	LD_{50} > 2000 mg/kg bw (both sexes and combined). All test subjects (5/5 males and 5/5 females) survived. One male exhibited	III	A

		ocular discharge on study day 1. All females (5/5) and 3/5 males exhibited dermal irritation between study days 1 and 13. No gross abnormalities observed at necropsy.		
Acute inhalation toxicity / rat PSL (Dayton, NJ) Study #38378/May 14, 2014 OCSPP 870.1300; OECD 403	49397906	LC_{50} > 2.13 mg/L (Nose-only, gravimetrically determined; both sexes and combined). Mean MMAD and GSD: 2.25 µm and 1.97 µm, respectively. All survived. All animals exhibited abnormal respiration, tremors and hypoactivity following exposure. In addition, the following clinical signs were observed: nasal discharge (5/5 males; 3/5 females), ocular discharge (4/5 males), and facial staining (2/5 females). All animals recovered by study day 9. All animals exhibited minor weight loss during the study, however all exceeded their initial weight by study termination (day 14). No gross abnormalities were observed at necropsy.	IV	A
Primary eye irritation / rabbit PSL (Dayton, NJ) Study #38379/May 14, 2014 OCSPP 870.2400; OECD 405	49397907	Corneal opacity was observed in all animals (3/3) from the 24 hour observation through the 48 hour observation, continuing in 2/3 through the 72 hour observation and in 1/3 through the day 4 observation. Iritis was observed in 1/3 from the 24 hour observation through the 48 hour observation. Grade 2-3 redness and/or chemosis was observed in all rabbits (3/3) at the one hour observation through the 48 hour observation, continuing in 2/3 through the day 4 observation. All scores "0" by the day 7 observation. MMTS = 29.7. Moderately irritating.	III	A

Primary dermal irritation / rabbit PSL (Dayton, NJ) Study #38380/May 15, 2014 OCSPP 870.2500; OECD 404	49397908	PDI = 1.9. Grade 1 erythema was observed in 2/3 subjects from the 30-60 minute observation through the 24 hour observation, increasing in severity in both animals to grade 2 erythema from the 48 hour observation through the 72 hour observation. The remaining subject exhibited grade 1 erythema from the 48 hour through the 72 hour observation. Grade 1 edema was observed in 2/3 from the 30-60 minute observation through the 72 hour observation. All scores were "0" by the day 7 observation, however 2/3 exhibited desquamation at the day 7 observation.	III	A
Dermal sensitization (Buehler)/Guinea Pig PSL (Dayton, NJ) Study #38381/May 23, 2014 OCSPP 870.2600; OECD 406	49397909	Product is a dermal sensitizer. Based on preliminary screening 100% test substance was selected for the induction phase and a 50% w/w mixture in distilled water for the challenge phase. A positive response (grade 1 or higher) was observed in 3/20 test animals at 24 hours after challenge and in 2/20 sites at 48 hours. No positive responses (grade 1 or higher) were observed in naïve control animals at 24 or 48 hours. Grade 1 erythema was observed in 5/10 positive control (100% HCA) animals at the 24 hour observation, continuing in 3/10 animals at the 48 hour observation.	YES	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap